PHARMACY BOARD[657]

Adopted and Filed

Rule making related to pharmacy support persons

The Board of Pharmacy hereby amends Chapter 5, "Pharmacy Support Persons," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76 and 155A.6B.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 155A.6B.

Purpose and Summary

These amendments are a result of an overall five-year review as required by Iowa Code section 17A.7(2). These amendments:

- Require pharmacy support persons to be registered prior to commencing employment in a pharmacy;
- Modify the structure of late renewal and reactivation processes and penalties to match the structure implemented for other licenses and registrations of the Board;
 - Allow the Board to assess a \$15 fee for written verification of a registration;
- Provide broader language relating to the delegation of nontechnical pharmacy functions to a pharmacy support person beyond those related solely to dispensing;
- Prohibit a license holder from requiring a supervising pharmacist to delegate function to a support person against the pharmacist's professional judgment;
- Require support persons to report to the Board, within 30 days, any criminal conviction or disciplinary action taken;
 - Simplify, clarify, and condense rules;
 - Incorporate language reflecting the Board's new online application process; and
 - Update references.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 13, 2021, as ARC 5374C.

The Board received comments from the Iowa Pharmacy Association (IPA) and from Walgreens. The comments expressed concern with the expectation that support persons must be registered prior to commencing employment in a pharmacy instead of the current 30-day grace period, and the IPA suggested a delayed implementation. The Board has implemented an online application process for pharmacy support persons which may be completed in a matter of minutes and which the Board has determined could be completed during an employee's onboarding process with all other employment documentation that is required (for benefits, payroll deductions, etc.). While the Board's online application will be operational well in advance of the May 12, 2021, effective date of this rule making, the Board has determined that an effective date of July 1, 2021, for the requirement related to registration of pharmacy support persons would allow the Board additional time to educate pharmacies about the online application opportunity. Therefore, rule 657—5.4(155A) was updated to provide a future effective date of the requirement for registration prior to commencing employment and retain language providing for the 30-day grace period through June 30, 2021.

Adoption of Rule Making

This rule making was adopted by the Board on March 10, 2021.

Fiscal Impact

It cannot be determined how many pharmacy support persons will request written verification of their registration when the Board's online verification system is free of charge. Also, while it is inherent that the Board will continue to process untimely renewal applications which result in the collection of late penalty fees or reactivation fees (except at this time due to the Governor's Proclamations), an estimate of the number of late renewals or reactivations cannot be determined. For renewal applications that are submitted within the first month after the registration has expired, the renewal fee and late penalty fee do not change from those that are currently assessed. Under these amendments, renewal applications that are submitted beyond the first month following expiration would include a fee of \$100 instead of the current fee of \$50.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on May 12, 2021.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—5.4(155A) as follows:

- 657—5.4(155A) Registration required. Unless exempt in rule 657—5.5(155A), any individual employed by a pharmacy who has direct access to prescription drugs or confidential patient information must be registered as a pharmacy support person. Beginning July 1, 2021, prior to commencing employment in an Iowa pharmacy as a pharmacy support person, an individual shall obtain registration as a pharmacy support person. Any registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in rule 657—5.14(155A).
- **5.4(1)** Effective date. Beginning June 1, 2010, a pharmacy support person shall register with the board pursuant to the requirements of this chapter.
- **5.4(2)** Registration number. Each pharmacy support person registered with the board will be assigned a unique registration number.
- **5.4(3)** Original application required. Any Through June 30, 2021, any person required to register and not previously registered with the board as a pharmacy support person shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy support person. Such application shall be received in the board office before the expiration of this 30-day period.

- **5.4(4)** Employment terminated. A registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in rule 657—5.14(155A).
 - ITEM 2. Amend rule 657—5.5(155A) as follows:
- 657—5.5(155A) Exempt from registration. Unless a person has direct access to prescription drugs, the The following shall be exempt from registration as a pharmacy support person:
- 1. Delivery person. A licensed pharmacist, registered pharmacist-intern, or registered pharmacy technician.
 - 2. Billing clerk, including a person who processes claims for third-party payments.
 - 3. Data processing support, maintenance, or programming personnel.
- 4. 2. Facility maintenance personnel including but not necessarily limited to cleaning, sanitation, structural, and mechanical maintenance personnel. Facility maintenance personnel deemed exempt from registration shall be directly supervised by a pharmacist or a certified pharmacy technician who is responsible for the maintenance person's activities within the pharmacy department to ensure medication security and patient privacy.
- 5. 3. Any person not directly employed by or under contract to the pharmacy, and not under the direct supervision of a pharmacist, who provides data processing, <u>data processing support</u>, <u>programming</u>, <u>maintenance</u>, <u>billing</u>, <u>maintenance</u>, <u>delivery</u>, or administrative support functions outside the pharmacy department.
 - 6. A registered pharmacist-intern or a registered pharmacy technician.
 - ITEM 3. Rescind paragraph 5.7(1)"b."
 - ITEM 4. Reletter paragraphs 5.7(1)"c" to "e" as 5.7(1)"b" to "d."
 - ITEM 5. Amend subrule 5.7(5) as follows:
- **5.7(5)** Sworn signature. The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate <u>nonrefundable</u> fees pursuant to <u>rules</u> <u>rule</u> 657—5.9(155A) and 657—5.11(155A).
 - ITEM 6. Rescind rule 657—5.9(155A) and adopt the following **new** rule in lieu thereof:

657—5.9(155A) Registration fee, term, and renewal.

- **5.9(1)** Fee. The nonrefundable application fee for a pharmacy support person registration shall be \$25. The nonrefundable application fee for a pharmacy support person registration shall be submitted in the form of a personal check, certified check, cashier's check, or money order made payable to the Iowa Board of Pharmacy when submitted with a written application or by acceptable debit or credit card when submitted with an online application.
- **5.9(2)** *Term.* A pharmacy support person registration shall expire on the second last day of the birth month following initial registration. Registration shall not require continuing education for renewal.
- **5.9(3)** *Renewal.* A pharmacy support person registration shall be renewed prior to the expiration of the registration.
- a. Delinquent registration grace period. A pharmacy support person registration which is not renewed prior to the expiration of the registration shall be considered delinquent. Renewal during the month following the expiration date of the registration shall include the nonrefundable registration fee pursuant to subrule 5.9(1) and a nonrefundable late penalty fee of \$25. A registered pharmacy support person who renews during the month following the expiration date of the registration shall not be subject to disciplinary action for continuing to practice as a pharmacy support person during the delinquency of the registration.
- b. Registration reactivation beyond grace period. If the registration is not renewed prior to the expiration of the one-month grace period identified in paragraph 5.9(3) "a," the individual shall cease practice as a pharmacy support person until the registration is reactivated. A pharmacy support person with an expired registration may apply for registration reactivation by submitting a completed application

for reactivation and a nonrefundable reactivation fee of \$100. An individual who continues employment as a pharmacy support person with an expired registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue practice as a pharmacy support person, may be subject to disciplinary sanctions.

- c. Voluntary cancellation. A registered pharmacy support person who ceases practice as a pharmacy support person and does not intend to renew the registration prior to its expiration may request that the board cancel the registration. If the pharmacy support person later seeks registration as a pharmacy support person, the individual shall not be assessed a late penalty fee or reactivation fee for renewal of the registration.
 - ITEM 7. Rescind and reserve rules **657—5.10(155A)** and **657—5.11(155A)**.
 - ITEM 8. Amend rule 657—5.13(155A) as follows:
- 657—5.13(155A) Registration certificates <u>verification</u>. The original registration certificate issued by the board to a pharmacy support person shall be maintained by the pharmacy support person. Verification of current registration shall be maintained in each pharmacy where the pharmacy support person is employed in that capacity and shall be available for inspection by the board. The board may require the submission of a nonrefundable fee of \$15 for written verification of a registration.
 - ITEM 9. Amend rule 657—5.14(155A) as follows:
- **657—5.14(155A) Notifications to the board.** A <u>registered</u> pharmacy support person shall report to the board within ten days a change of name, address, place of employment, or employment status.
 - ITEM 10. Amend rule 657—5.17(155A) as follows:
- **657—5.17(155A) Tasks a pharmacy support person shall not perform.** A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:
 - 1. to 8. No change.
- 9. Process or enter, including entry into the pharmacy computer system, pertinent clinical patient or prescription information, including entry of that information into the pharmacy computer system, except as provided in rule 657—5.18(155A) allergies and disease state information.
 - 10. to 14. No change.
- 15. Perform any of the duties identified in 657—Chapter 3 as technical functions <u>pursuant to</u> 657—Chapter 3 that may be delegated to a pharmacy technician.
 - ITEM 11. Rescind and reserve rule 657—5.18(155A).
 - ITEM 12. Rescind rule 657—5.21(155A) and adopt the following **new** rule in lieu thereof:
- 657—5.21(155A) Delegation of functions and responsibility of supervising pharmacist. Pursuant to established policies and procedures and the supervising pharmacist's professional judgment, a supervising pharmacist may delegate nontechnical functions in the operation of the pharmacy, except those which are prohibited pursuant to rule 657—5.17(155A), to an appropriately trained and registered pharmacy support person, but only if the pharmacist is on site and available to supervise the pharmacy support person when delegated functions are performed, except as provided in rule 657—6.7(124,155A) or 657—7.6(155A), as appropriate. The ultimate responsibility for the actions of a pharmacy support person shall remain with the supervising pharmacist. A pharmacy license holder shall not infringe on the authority of a supervising pharmacist to delegate or decline to delegate specific nontechnical functions to a pharmacy support person based on the supervising pharmacist's professional judgment regarding the knowledge and training of the pharmacy support person.

ITEM 13. Amend rule 657—5.25(147,155A), introductory paragraph, as follows:

657—5.25(147,155A) Unethical conduct or practice. Violation by a pharmacy support person of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—5.26(155A) 657—5.27(155A).

- ITEM 14. Renumber rule 657—5.26(155A) as 657—5.27(155A).
- ITEM 15. Adopt the following **new** rule 657—5.26(155A):

657—5.26(155A) Reporting discipline and criminal convictions. A registered pharmacy support person shall provide to the board written notice of and unredacted documents related to any disciplinary or enforcement action imposed by any licensing agency or regulatory authority on any license or registration held by the registered pharmacy support person no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registered pharmacy support person shall provide written notice and unredacted documents to the board of any criminal conviction that is related to the practice of pharmacy or controlled substances no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.

ITEM 16. Amend 657—Chapter 5, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 147.55, <u>147.80</u>, 155A.3, <u>155A.6B</u>, 155A.18 and 155A.23 and 2009 Iowa Code Supplement section 155A.6B.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/7/21.